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December 30, 2009

## VIA FEDERAL EXPRESS

The Honorable Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Administrative Office of the Courts
of the State of New
Jersey
Hughes Justice Complex
25 West Market Street
Trenton, NJ 08625

Civil Practice Division

**JAN 06 2009** 

RECEIVED

Re:

Response to the October 22, 2009 Application Pursuant to R. 4:38A for Designation of the Yaz/Yasmin/Ocella Litigation as a Mass Tort for Centralized Management

Dear Judge Grant:

We write on behalf of several law firms, whom together, represent hundreds of women alleging personal injury and other claims resulting from their ingestion of the oral contraceptives, Yaz®, Yasmin®, or Ocella®, and in response to the October 22, 2009 Application for Mass Tort Designation and Centralized Management of such cases, submitted by the Honorable Donald J. Volkert, Jr., of the Superior Court of New Jersey, Passaic Vicinage. We join in Judge Volkert's request that the Yaz®, Yasmin®, and Ocella® (collectively "Yaz/Yasmin litigation") be designated as a mass tort and be centralized for management in one of New Jersey's mass tort vicinages. For the reasons discussed below, we believe that Atlantic County is the most appropriate vicinage to manage what is expected to be a large and complex litigation.

## **Background Information Concerning the Products at Issue**

Yaz® and Yasmin® are slightly different formulations of an oral contraceptive containing the active ingredients ethinyl estradiol (an estrogen component) and drospirenone (a progestin component). Ocella® is the generic version of this medication.

These products, which are available by prescription only, are manufactured and/or marketed by the Defendants Bayer Healthcare Pharmaceuticals, Inc., Bayer Healthcare Corp., Bayer Corporation, Bayer AG, and Bayer Schering Pharma AG (collectively "Bayer Defendants"), and Barr Pharmaceuticals. The primary difference between the products at issue and other oral contraceptives on the market is their use of drospirenone, a progestin. Drospirenone is a "fourth generation" progestin that, prior to the approval of Yaz/Yasmin/Ocella was never marketed in the United States. In fact, other than another product manufactured by Bayer – a hormonal treatment for menopaure called Angeliq® – Yaz/Yasmin/Ocella are the only other drugs in the U.S. that contain drospirenone.

Plaintiffs, many of them very young woman, allege, in part, that as a result of ingesting Yaz®, Yasmin®, or Ocella®, they suffered serious injury, including deep vein thrombosis, pulmonary emboli, heart attack, and stroke. These contraceptives are also associated with an increased incidence of other serious injuries including gallbladder disease, pancreatitis, and heart dysrhythmia. In 2008 alone, fifty-nine deaths were reported to the FDA that were associated with the use of these birth control pills.

Plaintiffs' allegations are further supported a recent study published in the May 2008 edition of the British Medical Journal, The Venous Thrombotic Risk of Oral Contraceptives, Effects of Estrogen Dose and Progestogen Type: Results of the MEGA Case-Control Study, in which oral contraceptives containing drospirenone demonstrated a nearly twofold increased risk of venous thrombosis compared with oral contraceptives containing second generation progestins, and a sixfold increased risk compared with non-users of oral contraceptives.

Plaintiffs assert, in part, that Defendants were negligent in their development, testing, marketing, promotion, and advertising of the products at issue, and ignored important safety signals relating to their products. Further, Plaintiffs allege that the product labeling and promotional materials supplied to consumers and the medical community were fraudulent and misleading. Plaintiffs expect Defendants to vigorously defend themselves against the claims at issue, and that the Yaz/Yasmin Litigation will involve complex scientific and regulatory issues relating to the development, approval, and marketing of these birth control products.

Plaintiffs estimate that as of the date of this correspondence, there are approximately 175 Yaz®, Yasmin®, or Ocella® cases filed in various New Jersey Courts. In addition to those cases that were filed in Passaic County and which were referenced by Judge Volkert in his October 22, 2009 Application, the attorneys submitting this Response have filed 161 cases in various counties throughout New Jersey. See Exhibit A annexed hereto. Given the large number of inquiries received from claimants thus far, we estimate that total number of cases in the Yaz/Yasmin Litigation may be in the hundreds.

## **Mass Tort Designation Is Warranted**

Pursuant to R. 4:38A, it is respectfully submitted that this litigation warrants designation as a Mass Tort because it will involve a large number of plaintiffs who are as geographically dispersed as the products at issue. Indeed, Yaz®, Yasmin®, and Ocella® and sold throughout the United States. The current actions on file involve Plaintiffs from a number of different states. Finally, like other mass torts before it, the cases will likely involve hundreds of claims with recurrent and complex issues of law and fact.

For example, although there are three products at issue, Yaz®, Yasmin® and Ocella®, they each contain the same active ingredients and are manufactured by the same Defendants. Thus, the liability and causation issues of these cases are associated with a substantially similar products containing the same active ingredients. Similarly, Bayer HealthCare Pharmaceuticals Inc. and Barr Pharmaceuticals are New Jersey based companies, responsible for the design, development, research, testing, manufacture, packaging, promotion, marketing, distribution and/or sale of the products at issue. Much of the discovery needed to prosecute these cases will involve these Defendants. Further, there is commonality of injury and/or damages among the various claimants, as plaintiffs allege injuries including deep vein thrombosis, pulmonary emboli, heart attack, stroke, gallbladder disease, pancreatitis, and heart dysrhythmia.

The opportunity to designate these cases as a Mass Tort for centralized management comes at the early stages of this litigation, where coordinated discovery and pre-trial proceedings will inure to the benefit of all parties to the countless additional actions to be filed in New Jersey. The Judicial Panel on Multidistrict Litigation has already centralized the federal Yaz/Yasmin (drospirenone) cases as part of MDL No. 2100, before the Honorable Judge David R. Herndon, United States District Court for the Southern District of Illinois. Similarly, more than 170 Yaz/Yasmin cases have been consolidated as a mass tort before the Honorable Sandra Moss, Commonwealth of Pennsylvania, Philadelphia Court of Common Pleas. Centralized management of these cases in New Jersey at this time will encourage cooperation between the various jurisdictions. Indeed, many of the attorneys who are signatories to this letter have cases in the MDL and/or the Philadelphia litigation, and centralized management of the New Jersey Yaz/Yasmin/Ocella cases will help insure coordination between state and federal litigations.

### Atlantic County is the Appropriate Vicinage for Centralized Management

Plaintiffs believe that Atlantic County is the most appropriate vicinage for the centralized management of the Yaz/Yasmin/Ocella litigation. There are three important factors to consider when selecting the best venue in which to centralize a mass tort: (1) fairness; (2) geographic location of the parties and attorneys; and (3) "the existing civil and mass tort caseload in the vicinage." See Mass Torts- Revised Guidelines and Criteria for Designation, at 3 (October 25, 2007).

With respect to the "fairness" component of this determination, we do not believe that any of the mass tort vicinages will be an "unfair" venue for the parties. Although there may be a number of Plaintiffs with a relationship to Atlantic County, because of the size of the litigation there will be many Plaintiffs who have no relationship to any particular county. Thus, this factor, alone, should not be determinative. Further, as neither the Defendants nor the majority of plaintiffs have a strong connection to Atlantic County, there should be no concerns about potential jurors showing favoritism to a local party.

Plaintiffs note, however, that this is a complex pharmaceutical products liability litigation, which will likely involve hundreds of cases. Such cases will involve complex issues relating to the underlying science, development, marketing, and regulation of the pharmaceutical products at issue. The Honorable Carol E. Higbee, who presides over mass torts in Atlantic County, has significant experience in pharmaceutical litigation and would be well-suited to the management of these cases. As the Court is aware, Judge Higbee played a significant role in the resolution of the Vioxx® litigation, where she managed more than 15,000 cases filed in New Jersey.

The Atlantic County venue is also convenient to the parties, witnesses, and their attorneys, as it is within a reasonable driving distance from several regional and international airports in Atlantic City, Philadelphia, and Newark. There is also frequent and affordable train service from Philadelphia to Atlantic City. Further, Atlantic County is the most convenient vicinage for those Defendants located in Pennsylvania. If the New Jersey cases are coordinated in Atlantic City, its proximity to Philadelphia (where the Pennsylvania Yaz/Yasmin litigation is consolidated) will facilitate coordination of these related proceedings.

The final consideration, "the existing civil and mass tort caseloads in the vicinage" supports the selection of Atlantic County for centralization and management of the Yaz/Yasmin Litigation. Of the three available mass tort vicinages, Atlantic County is best equipped —with respect to staffing and facilities—to manage a litigation involving a large number of attorneys and hundreds of cases. Further, when considering the caseloads of the respective venues, we note that there are currently 7 mass torts centralized in Middlesex County, including Asbestos, Ciba-Geigy, Gadolinium, HRT, Ortho Evra, Risperdal/Seroquel/Zyprexa and Zometa/Aredia. By contrast, there are only 6 mass torts centralized in Atlantic County and two of these have settled, and thus have limited activity. They include: Accutane, Fosamax, Levaquin, Bextra/Celebrex (settled), Vioxx (settled), and Bristol-Myers Squibb Environmental. While the Bergen County venue currently has fewer mass torts, Plaintiffs believe that the reasons detailed above firmly tip the scales in favor of Atlantic City for this particular litigation. Therefore, we respectfully submit that Atlantic County is the most appropriate vicinage in which to centralize management of the Yaz/Yasmin litigation.

For the above stated reasons, we respectfully request that the Yaz®, Yasmin®, and Ocella® cases be designated as a Mass Tort pursuant to R. 4:38A, and that such cases be centralized for management in the Atlantic County vicinage.

## Respectfully submitted



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cc: Michelle V Perone, Esq., Chief Civil Court Programs (via overnight delivery)
The Honorable Carol Higbee (via overnight delivery)
Susan Sharko, Esq. (Counsel for Defendants) (via overnight delivery)

# EXHIBIT A

## Exhibit A Listing of Cases Filed by Submitting Attorneys

DOUGLAS & LO	NDON
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New York, New Y	ork 10038

Tel. (212) 566-7500

Case Caption_	Docket No.	Filing Location
Amy Bentley v. Bayer	L - 004914 09	Atlantic County
Corporation, et al.	L = 004314 03	Additio County
Jennifer Canon v. Bay	er L = 004916 09	Atlantic County
Corporation, et al.	L = 004910 09	Attaintic County
Tamlyn Diulio v. Baye	L - 004120 09	Atlantic County
Corporation, et al.	12-004120 09	Atlantic County
Dana Michaels v. Baye	Docket Number Pending	Atlantic County
Corporation, et al.	Docket Number Fending	Attaintic County
Carrie Powell v. Bayer	L-004915 09	Atlantic County
Corporation, et al.	L = 004913 09	Attainte County
Pamela Slone v. Bayer	L - 004629 09	Atlantic County
Corporation, et al.	L - 004029 09	Attaille County
Maggie Tipton v. Baye	L - 004809 09	Atlantic County
Corporation, et al.	L - 004809 09	Atlantic County
Total No. of Cases:	7	

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Case Caption	Docket No.	Filing Location
Kylie Brown v. Bayer Corporation, et al.	L-5116-09	Atlantic County
Total No. of Cases:	1	

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Tel. (212) 421-2800

Case Caption	Docket No.	Filing Location
Jennifer Arnder and Sha	iwn	
Arnder v. Bayer Corporation, et al.	L-4418-09-MT	Atlantic County

Tanaina Antlana Davian		Γ
Jessica Astle v. Bayer	L-4901-09-MT	·Atlantic County
Corporation, et al.		
Kimberly Barbetta &	T 4056 00	
Robert Barbetta v. Bayer	L-4956-09	Atlantic County
Corporation, et al.		
Delores Bochenek &		
Charles Bochenek v. Bayer	L-4955-09	Atlantic County
Corporation, et al.		
Samantha Jo Boettge v.	L-5066-09-MT	Atlantic County
Bayer Corporation, et al.	2 3000 05 1111	Titiantic County
Tracy Bohannon & Tommy		
Bohannon v. Bayer	L-4239-09-MT	Atlantic County
Corporation, et al.		
Jennifer Breva & Manuel		
Breva v. Bayer Corporation,	L-5062-09-MT	Atlantic County
et al.		
Shannon Brockman v.	L-4803-09-MT	Atlantic County
Bayer Corporation, et al.	L-4003-07-W11	Analitic County
Stacia Brooks & Antjuan		
Brooks v. Bayer	Docket Number Pending	Atlantic County
Corporation, et al.		
Elizabeth Button and		
Christopher Button,	L-4791-09-MT	Adlantia Gaustia
Plaintiff, v. Bayer	L-4/91-09-M1	Atlantic County
Corporation, et al.		
Lisa Clement and James		
Clement on behalf of Kori	L-4786-09-MT	Adlantia Gaustia
Clement v. Bayer	L-4/86-09-M1	Atlantic County
Corporation, et al.		
Caitlin Coleman v. Bayer	I 4790 00 MT	Adlantia Commi
Corporation, et al.	L-4789-09-MT	Atlantic County
Melody Collins v. Bayer	I 4000 00 3 m	Adams G
Corporation, et al.	L-4800-09-MT	Atlantic County
Clarissa Doyon & Daniel		
Doyon v. Bayer	Docket Number Pending	Atlantic County
Corporation, et al.		
Wendy Duchscher on		
behalf of Cherrelle Crandall	L-4776-09-MT	Atlantic County
v. Bayer Corporation, et al.		
Kala Foster v. Bayer	D 1	
Corporation, et al.	Docket Number Pending	Atlantic County
Jessca Gammons v. Bayer		
Corporation, et al.	Docket Number Pending	Atlantic County
Donna Geraghty & James		
Geraghty v. Bayer	L-5064-09-MT	Atlantic County
Corporation, et al.		
Corporation, et al.		

Gina Giannattasio, v. Bayer	I 4700 00 MT	Adami's Country
Corporation, et al.	L-4790-09-MT	Atlantic County
Elbony Godwin and Luther		
Godwin v. Bayer	L-4792-09-MT	Atlantic County
Corporation, et al.		
Mindy Gunn & Thomas		
Gunn on Behalf of Caroline	L-4787-09-MT	Atlantic County
Gunn, Plaintiff, v. Bayer	B-4767-05-1411	7 thantie County
Corporation, et al.		
Susan Hill v. Bayer	L-4806-09-MT	Atlantic County
Corporation, et al.		
Carissa Hoium & Michael		
Hoium v. Bayer	L-5065-09-MT	Atlantic County
Corporation, et al.		
Melanie James and Franklin	I 4427 00 MT	Adami - Carri
James v. Bayer	L-4427-09-MT	Atlantic County
Corporation, et al.		
Kimberly Jeter v. Bayer	Docket Number Pending	Atlantic County
Corporation, et al.  Kristen Johnson and		
Rodney Johnson v. Bayer	L-4783-09-MT	Atlantia County
Corporation, et al.	L-4/63-09-WH	Atlantic County
Hermila Loera v. Bayer		
Corporation, et al.	L-4958-09	Atlantic County
Beth London v. Bayer		
Corporation, et al.	L-5061-09-MT	Atlantic County
Amanda Mach v. Bayer		
Corporation, et al.	L-5063-09-MT	Atlantic County
Tadra Mack and Richard		
Mack v. Bayer Corporation,	L-4798-09-MT	Atlantic County
et al.	2 1170 07 1111	Triangle County
Ina Mathis v. Bayer	I 4704 00 15T	
Corporation, et al.	L-4784-09-MT	Atlantic County
Heiedi McGough & Joseph		
McGough v. Bayer	L-4957-09	Atlantic County
Corporation, et al.		-
Diane Olivares & Oscar		
Olivares v. Bayer	Docket Number Pending	Atlantic County
Corporation, et al.		
Kimberly Oslin and Vernon		
Oslin v. Bayer Corporation,	L-4423-09-MT	Atlantic County
et al.		
Amanda Padilla v. Bayer		
Corporation, et al.	Docket Number Pending	Atlantic County
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Amparo Pena and Heriberto Pena v. Bayer Corporation, et al.	L-4426-09-MT	Atlantic County
Cierra Pettit & Brandon		
Pettit v. Bayer Corporation,	L-4954-09	Atlantic County
et al.		,
Brooke Pequete v. Bayer	Doolset Number Bonding	Atlantia County
Corporation, et al.	Docket Number Pending	Atlantic County
Megan Ridnor and Kenneth		
Ridnor v. Bayer	L-4793-09-MT	Atlantic County
Corporation, et al.		
Connie Rossman v. Bayer	L-4799-09-MT	Atlantic County
Corporation, et al.	E-1755-05-W11	Attantic County
Christina Salaiz and Jordan		
Salaiz v. Bayer	L-4777-09-MT	Atlantic County
Corporation, et al.		
Amy Schotch and Craig		
Schotch v. Bayer	L-4426-09-MT	Atlantic County
Corporation, et al.		
Tausha Shiffer and Jason		
Shiffer v. Bayer	L-4428-09-MT	Atlantic County
Corporation, et al.		
Mary Sierra v. Bayer	L-4959-09	Atlantic County
Corporation, et al.		
Tabitha Spizuoco and	I 4417.00 MT	All is G
David Spizuoco v. Bayer Corporation, et al.	L-4417-09-MT	Atlantic County
Maria Verdone v. Bayer		
Corporation, et al.	L-4804-09-MT	Atlantic County
Maria Villanueve v. Bayer		
Corporation, et al.	L-4802-09-MT	Atlantic County
Total No. of Cases:	47	
i viai ivo. vi Cases.	77	

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Philadelphia, PA 19106

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Case Caption	Docket No.	Filing Location
Tina Petrarca v. Bayer Corporation, et al.	L-004025-09	Atlantic County
Sophia Loren Stanley v. Bayer Corporation, et al.	L-004021-09	Atlantic County
Rosalie Szabo v. Bayer Corporation, et al.	L-004175-09	Atlantic County

Deborah J. Tirjan v. Bayer	L-004018-09	Atlantic County
Corporation, et al.	E-004018-03	Titiantic County
Dawn Marie Wallace v.	L-004391-09	Atlantic County
Bayer Corporation, et al.	L-004371-07	Atlantic County
Total No. of Cases:	5	

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Case Caption	Docket No.	Filing Location
Cora Adams v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Jamie Backhaus v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Contance Chang-Gillespie v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Briana Cohea v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Rosa Cornier v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Shanna Cox v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Megan Grodek v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Jessica Harris v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Sharon Jordan v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Breann Livermore v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Melissa Norris v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Amber Shrimpton v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Amber Sitar v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Lauren Tate v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Jerri Taylor v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Total No. of Cases:	15	

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Facsimile: 212.355.9592

Case Caption	Docket No.	Filing Location
Candice L. Atkinson v.	ATL-L-4107-09	Atlantic County
Melissa Boecker v. Bayer	ATL-L-4841-09	Atlantic County
Corporation, et al.  Diana Delgado v. Bayer Corporation, et al.	ATL-L-4840-09	Atlantic County
Cynthia Maddock v. Bayer Corporation, et al.	ATL-L-4842-09	Atlantic County
Theresa Taylor v. Bayer Corporation, et al.	ATL-L-4661-09	Atlantic County
Elizateth Tripodi v Bayer Corporation, et al.	ATL-L-4843-09	Atlantic County
Tajuana Turner v. Bayer Corporation, et al.	ATL-L-5007-09	Atlantic County
Maria Vara v. Bayer Corporation, et al.	ATL-L-4844-09	Atlantic County
Mae Walker v. Bayer Corporation, et al.	ATL-L-4660-09	Atlantic County
Total No. of Cases:	9	
	9	

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fax (646) 390-3061

Case Caption	Docket No.	Filing Location
Stephanie Clark v. Bayer	Docket Number Pending	Atlantic County
Corporation, et al.	Docket Number Fending	Atlantic County
Jamie Crawford v. Bayer	Dealest Number Panding	Atlantia County
Corporation, et al.	Docket Number Pending	Atlantic County
Tabitha Edwards v. Bayer		
Corporation, et al.	Docket Number Pending	Atlantic County

Darla Wise v. Bayer Corporation, et al.	r	Docket Number Pending	Atlantic County
Total No. of Cases:	1	4	
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Case Caption	Docket No.	Filing Location
Judy Darby v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
LaTorrie Glover v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Alissa Hall v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Trista Williams v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Total No. of Cases:	4	

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Fax 1 (201) 399-5856

Case Caption	Docket No.	Filing Location
Brooke Conrad v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Mary Katherine Davison v. Bayer Corporation, et al.	L-4725-09	Atlantic County
Nicole Goode v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Joelle Smith v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
JoAnn Stuyvenberg v. Bayer Corporation, et al.	Docket Number Pending	Atlantic County
Jody Terwilliger v. Bayer Corporation, et al.	L-4727-09	Atlantic County
Total No. of Cases:	6	

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Tel. (717) 892-3000 Fax (717) 892-1200

Case Caption	Docket No.	Filing Lecation
Shirley Agosto v. Bayer Corp., et al.	L-4089-09	Atlantic County
Allison Browning v. Bayer Corp., et al.	L-3158-09	Atlantic County
Erica Burke v. Bayer Corp., et al.	L-4080-09	Atlantic County
Heather McKellick v. Bayer Corp., et al.	L-3160-09	Atlantic County
Kelsey Ann Pavek v. Bayer Corp., et al.	L-4080-09	Atlantic County
Victoria Redman v. Bayer Corp., et al.	L-4079-09	Atlantic County
Total No. of Cases:	6	

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973-639-9100 Fax: 973-639-9393

Case Caption	Docket No.	Filing Location
Virginia Allen & Jimmy		
Allen v. Bayer Corporation,	L-4547-09	Atlantic County
et al.		
Jina Ash v. Bayer	L-4517-09	Atlantic County
Corporation, et al.	E-4317-09	Attainte County
Sharon Bach v. Bayer	L-4356-09	Atlantic County
Corporation, et al.	D-4330-07	Attainte County
Eva Barnes v. Bayer	L-4982-09	Atlantic County
Corporation, et al.	L-4702-07	Attainte County
Mary Beth Cattrton v.	L-4519-09	Atlantic County
Bayer Corporation, et al.	D-4317-07	Atlantic County
Tara Berwick & Tom		
Berwick v. Bayer	L-5077-09	Atlantic County
Corporation, et al.		
Starla Bufford v. Bayer	L-4518-09	Atlantic County
Corporation, et al.	L-4310-07	Titlantic County

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Rebecca Burleson v. Bayer Corporation, et al.	L-4980-09	Atlantic County
Crystal Christian & Steven		
Christian v. Bayer	L-5078-09	Atlantic County
Corporation, et al.		
Jewelletta Clark v. Bayer	T 4005 00	
Corporation, et al.	L-4935-09	Atlantic County
Rachel Conley & Ryan		
Conley v. Bayer	L-4548-09	Atlantic County
Corporation, et al.	·	
Deborah Dixon v. Bayer	L-4520-09	Atlantia County
Corporation, et al.	L-4320-09	Atlantic County
Lynita Dorsey v. Bayer	L-5074-09	Atlantic County
Corporation, et al.	L-3074-09	Atlantic County
Daniella Drobis v. Bayer	L-4521-09	Atlantic County
Corporation, et al.	L-4321-09	Attailite County
Ashley Dunford v. Bayer	L-5085-09	Atlantic County
Corporation, et al.	D-5005-07	Attaine County
Tiffany Dubroc v. Bayer	L-4513-09	Atlantic County
Corporation, et al.	L-4313-07	Adamic County
Lakiah Edwin v. Bayer	L-5076-09	Atlantic County
Corporation, et al.	E-3070-09	Additio County
Aislinn Ellis & Anthony		
Hamdan v. Bayer	L-4581-09	Atlantic County
Corporation, et al.		
Gwendolyn Forman-Grisby		
& Andrew Grisby v. Bayer	L-4582-09	Atlantic County
Corporation, et al.		
Carmen Gates v. Bayer	L-4973-09	Atlantic County
Corporation, et al.		Transfer Country
Sarah Gonzales v. Bayer	L-4112-09	Atlantic County
Corporation, et al.		
Katherine Grundt v. Bayer	L-5086-09	Atlantic County
Corporation, et al.		
Danielle Hayes v. Bayer	L-4514-09	Atlantic County
Corporation, et al.		
Lisa Hernandez & Christian	1 4590 00	Adamia Carri
Hernandez v. Bayer	L-4580-09	Atlantic County
Charity Hyakahy & Jasan		
Chasity Huckeby & Jason Huckeby v. Bayer	L-4543-09	Atlantia County
Corporation, et al.	L-4343-09	Atlantic County
Lisa Iams & Dennis Iams v.		
Bayer Corporation, et al.		
Dayer Corporation, et al.	L-4976-09	Atlantic County

Total No. of Cases:	49	
Corporation, et al.		
& Brent Mapp v. Bayer	L-4933-09	Atlantic County
Wendy Zimmerman-Mapp		
Corporation, et al.	L-43/9-09	Atlantic County
Tonya Woods v. Bayer	L-4579-09	Atlantia County
Corporation, et al.	L-4774-09	Atlantic County
Aletha Whitmore v. Bayer	I 4774 00	Adlandia Garreta

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Ellen Relkin, Esq. Paul Pennock, Esq. 700 Broadway

New York, New York 10003

Tel. (212) 558-5715 Fax: 212-344-5461

Case Caption	Docket No.	Filing Location
Jamie Platt v. Bayer Corporation, et al.	L-5124 09	Atlantic County
Maria Remuszka v. Bayer Corporation, et al.	L-5123 09	Atlantic County
Carmella Rudi v. Bayer Corporation, et al.	L-5125 09	Atlantic County
Total No. of Cases:	3	

David W. Zoll

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6620 W. Central Ave.

**Toledo, OH 43617** 

(419) 841-9623

(417) 041-7023		
Case Caption	Docket No.	Filing Location
Elizabeth Bartja et al. v.	Design Number Design	Atlantic County
Bayer Healthcare Inc	Docket Number Pending	
Joanne Brooks v. Bayer	1 004976 00	Atlantic County
Healthcare Inc.	L-004876 09	
Heather Mitchell v. Bayer	L-004875 09	Atlantic County
Healthcare Inc.		
Shemeley, et al. v. Bayer	Dooloot Namehou Dougling	Atlantic County
Healthcare Inc	Docket Number Pending	
Holly Williams et al. v.	Docket Number Pending	Atlantic County
Bayer Healthcare Inc		
Total No. of Cases:	5	
TOTAL NO. OF CASES	161	

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Civil Practice Division

JAN 06 2009

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December 30, 2009

### VIA FEDERAL EXPRESS

The Honorable Glenn A. Grant, J.A.D.
Acting Administrative Director of the Courts
Administrative Office of the Courts
Richard J. Hughes Justice Complex
25 West Market Street
P.O. Box 037
Trenton, New Jersey 08625

Re:

Defendants' Comments Regarding Designation of Site for Central Management of the YAZ®/Yasmin®/Ocella® Litigation

Pursuant to R. 4:38A

Dear Judge Grant:

We represent defendants Bayer Corporation, Bayer HealthCare LLC, and Bayer HealthCare Pharmaceuticals Inc. (collectively, "Bayer") in the 114 pending cases in New Jersey involving the prescription medications YAZ®, Yasmin®, and/or Ocella®.¹ Pursuant to Rule 4:38A and AOC Directive #7-09 Mass Torts Guidelines and Criteria for Designation, we submit this letter in response to the application filed by Judge Donald J. Volkert, Jr., seeking to have the YAZ/Yasmin/Ocella litigation in New Jersey designated as a mass tort. We respectfully request that the litigation be consolidated for centralized management in Bergen County.

Edward A. Gramigna, Jr. Partner responsible for Florham Park Office

Established 1849

<sup>&</sup>lt;sup>1</sup> Some suits also name foreign defendants, including those identified as Bayer AG and Bayer Schering Pharma AG. To date, these foreign defendants have not been served in, and have not appeared in, any New Jersey case.

Hon. Glenn A. Grant, J.A.D. December 30, 2009 Page 2

#### I. BACKGROUND ON THE YAZ/YASMIN/OCELLA LITIGATION

This litigation pertains to plaintiffs' individual claims arising from the use of YAZ, Yasmin, and/or Ocella, which are FDA-approved oral contraceptive prescription medications containing drospirenone and ethinyl estradiol. Bayer HealthCare Pharmaceuticals Inc. sells and markets Yasmin and YAZ in the United States. Ocella is a generic version of Yasmin that is marketed by Barr in the United States. The FDA has approved YAZ and Yasmin as safe and effective for oral contraceptive use as recommended in the medicines' labeling. The FDA also has approved YAZ for the treatment of Premenstrual Dysphoric Disorder ("PMDD") and moderate acne in certain women who also choose to use an oral contraceptive for birth control.

Plaintiffs in the pending New Jersey consolidated proceedings are approximately 114 individuals (excluding spouses) who reside in at least 36 states, including the State of New Jersey.<sup>2</sup> Lawsuits alleging injury from the use of YAZ, Yasmin and/or Ocella also are pending in other states and in federal court. The federal cases have been coordinated into a multidistrict litigation in the Southern District of Illinois (MDL No. 2100, *In Re: Yasmin and YAZ (Drospirenone) Marketing, Sales Practices and Products Liability* 

<sup>&</sup>lt;sup>2</sup> As of December 29, 2009, approximately 114 cases involving Yaz, Yasmin, and/or Ocella have been filed in the State of New Jersey. One hundred four of these cases are pending in Atlantic County; and 10 cases are pending in Passaic County. Although the majority of the cases have been filed by plaintiffs in Atlantic County, this should not be a consideration, because Atlantic County has no particular connection with the litigation, especially as no activity in the litigation has commenced there. In fact, no discovery has been taken in any of the New Jersey cases, and in most cases, answers have not yet been filed.

Hon. Glenn A. Grant, J.A.D. December 30, 2009 Page 3

Litigation), before Chief Judge David R. Herndon. Additionally, there is a state-court coordinated proceeding in Philadelphia, Pennsylvania, and a petition to coordinate California state-court cases pending in California.

Most of the complaints allege product liability claims relating to the use of YAZ, Yasmin and/or Ocella. The complaints seek a variety of relief.

Discovery has commenced in MDL-2100 and the Philadelphia Coordinated proceedings. Bayer has produced more than 1.7 million pages of documents to date and anticipates producing more than an additional million pages in late December. Total document production is expected to be many millions of pages.

#### II. THE VENUE

Consideration of the relevant factors – the existing civil and mass tort caseloads, geographic location of parties and attorneys, and fairness – leads to the conclusion that Bergen County provides the most appropriate vicinage for centralized management. See Mass Torts Guidelines and Criteria for Designation, at 2 (August 18, 2009).

Existing civil and mass tort caseloads. Based on the pending civil and mass tort caseloads in New Jersey state courts, Bergen County is the best vicinage for this litigation. As of November 30, 2009, Bergen County had, by far, the fewest mass tort

Hon. Glenn A. Grant, J.A.D. December 30, 2009 Page 4

Bergen County, for instance, Atlantic County had two times the number of mass tort litigations and nearly five times the number of active, pend ag mass tort cases. And, again compared to Bergen County, Middlesex County had more than two times the number of mass tort litigations and nearly seventeen times the number of active, pending mass tort cases:

- Bergen County: three (3) mass tort litigations (Judge Brian Martinotti presides over Digitek, Mahwah Toxic Dump Site, and NuvaRing) with a total of 280 active, pending mass tort cases.
- Middlesex County: seven (7) mass tort litigations (Judge Jessica Mayer presides over Gadolinium, HRT, ORTHO EVRA®, Risperdal®/Seroquel/ Zyprexa, and Zometa/Aredia, and Judge Ann McCormick presides over asbestos and Ciba Geigy) with a total of 4,658 active, pending mass tort cases.
- Atlantic County: six (6) mass tort litigations (Judge Carol Higbee currently presides over Accutane, Bextra/Celebrex, Bristol-Myers-Squibb Environmental, Fosamax, Levaquin, and Vioxx, and also oversees the centralized management of the Stryker Trident Hip Implant Litigation) with a total of 1,310 active, pending mass tort cases.

Bergen County is best equipped to handle the large volume of cases that will be consolidated in the YAZ/Yasmin/Ocella litigation.

<sup>&</sup>lt;sup>3</sup> See Mass Tort Information Center, available at http://www.judiciary.state.nj.us/mass-tort/index.htm (last visited Dec. 30, 2009); New Jersey Judiciary Court Management (November 2009), available at http://www.judiciary.state.nj.us/quant/cman0911.pdf (last visited Dec. 30, 2009), at pp. 8, 10, 30.

Hon. Glenn A. Grant, J.A.D.

December 30, 2009

Page 5

Geographic location of parties and attorneys, and fairness. Bergen County also

is a geographically superior location for all interested parties in this consolidated

litigation. Bayer HealthCare Pharmaceuticals Inc. maintains i.s world headquarters and

principal place of business in Wayne, New Jersey (Passaic County), which is near Bergen

County. As such, many of the relevant employees and documents are located in northern

New Jersey. Plaintiffs, and their counsel, come from across the United States, and have

no interest in any particular location in New Jersey. If anything, Bergen County would

be an ideal and fair location for the plaintiffs, witnesses, and attorneys from other states

and countries because it is conveniently located close to three major airports – Newark

Liberty International Airport, La Guardia Airport, and John F. Kennedy International

Airport.

CONCLUSION

In light of existing case loads, presently available judicial resources and capacity,

the geographic location, and ease of accessibility, Bayer submits that the appropriate

venue for centralization of the YAZ/Yasmin/Ocella litigation is Bergen County.

Respectfully Submitted,

DRINKER BIDDLE & REATH LLP

Jusan M. Sharko

Susan M. Sharko

Hon. Glenn A. Grant, J.A.D. December 30, 2009
Page 6

Cc: Honorable Donald J. Volkert, Jr., A.J.S.C. (via Federal Express)

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Esther Berezofsky, Esq. (via facsimile and first-class mail)

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Peter E. Goss, Esq. (via facsimile and first-class mail)

Catherine T. Heacox, Esq. (via facsimile and first-class mail)

Regina Sharlow Johnson, Esq. (via facsimile and first-class mail)

Christopher A. Seeger, Esq. (via facsimile and first-class mail) Michael Weinkowitz, Esq. (via facsimile and first-class mail)

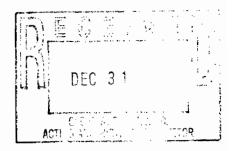
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December 30, 2009

#### VIA FEDERAL EXPRESS

The Honorable Glenn A. Grant
Acting Administrative Director of the Courts
Administrative Office of the Courts
P.O. Box 037
Trenton, NJ 08625-0037



RE: Comment on Application for Mass Tort Designation and Centralized Management of Litigation Involving Yas, Yasmin, and Ocella

Request to Formally Change the Nomenclature Used Within the New Jersey Court System to Describe Cases Centralized for Management Under R. 4:38A.

Dear Judge Grant,

The New Jersey Lawsuit Reform Alliance (NJLRA) submits this letter to respectfully request that the Administrative Office of the Courts and the New Jersey Supreme Court consider changing the nomenclature used within the New Jersey court system to describe cases centralized for management under R. 4:38A. Without opinion regarding the designation of the Yaz, Yasmin, and Ocella litigations, NJLRA asks for the elimination of "mass torts" in future centralizations, and replacement of this nomenclature with "centralized management."

NJLRA concurs with the opinion expressed by the New Jersey Defense Association (NJDA), which asserts that the nomenclature used within R. 4:38A, the Guidelines, and the Information Center is unnecessarily prejudicial to defendants, and should be revised in favor of neutral nomenclature.

NJLRA further supports the change in nomenclature proposed by the NJDA, which would revise  $\underline{R}$ : 4:38A to read as follows:

**RULE 4:38A. Centralized Management** 

The Supreme Court may designate a case or category of cases to receive centralized management in accordance with criteria and procedures promulgated by the Administrative Director of the Courts upon approval by the Court. Promulgation of the criteria and procedures will include posting the Centralized Management Information Center on the Judiciary's Internet website, http://www.judiciary.state.nj.us.

NJLRA agrees that implementation of the aforementioned change in nomenclature would remedy a long-standing bias within the current system. Thank you in advance for your consideration.

Respectfully submitted,

Civil Practice Division

New Jersey Lawsuit Reform Alliance

JAN 05 2009

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By: Marcus Rayner, Executive Director

AEM:mnr



## New Jersey Defense Association

Civil Practice Division

JAN 05 2009

Please reply to:

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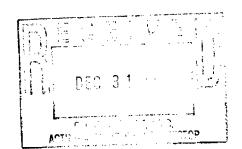
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December 30, 2009

## VIA FEDERAL EXPRESS

The Honorable Glenn A. Grant
Acting Administrative Director of the Courts
Administrative Office of the Courts
P.O. Box 037
Trenton, NJ 08625-0037



Re:

Comment on Application for Mass Tort Designation and Centralized Management of Litigation Involving Yaz, Yasmin, and Ocella

Request to Formally Change the Nomenclature Used Within the New Jersey Court System to Describe Cases Centralized for Management Under R. 4:38A.

Dear Judge Grant:

This letter is submitted on behalf of the New Jersey Defense Association ("NJDA"). We write in response to the subject application and to respectfully request that the Administrative Office of the Courts, and ultimately, the New Jersey Supreme Court, consider a change in the nomenclature used within the New Jersey court system to describe cases centralized for management under R. 4:38A. NJDA does not express any opinion on whether the Yaz, Yasmin, or Ocella litigations should be designated for centralized management and leave that issue for the parties themselves to argue, but ask the Court, in the event of a centralization of such litigations and for future centralizations, to eliminate references to "mass torts" in its nomenclature, and

DRISTATE REPRESENTATIVE to replace such references with "centralized management." 30 Columbia Tumpike

The Honorable Glenn A. Grant December 30, 2009 Page 2.

## I. Rule 4:38A and The Judiciary's Mass Tort Information Center

Rule 4:38A currently governs the designation of cases for centralized management. The rule provides:

RULE 4:38A. Centralized Management of Mass Torts

The Supreme Court may designate a case or category of cases as a mass tort to receive centralized management in accordance with criteria and procedures promulgated by the Administrative Director of the Courts upon approval by the Court. Promulgation of the criteria and procedures will include posting in the Mass Tort Information Center on the Judiciary's Internet website (www.judiciary.state.nj.us).

On August 18, 2009, the Court revised the approved criteria and procedures for the centralization of cases as a "mass tort" pursuant to R. 4:38A (the "Guidelines). The Guidelines afford interested parties an opportunity to provide the Court with relevant information prior to a determination of whether to designate a category of cases for centralized management. The Guidelines also inform the public on how the Court makes such a determination, and thus, what information may be relevant.

The court system uses its Internet-based Mass Tort Information Center (the "Information Center") to communicate information concerning centralized cases with the public. At the Information Center, the court system posts important notices required by the new Guidelines, as well as information about the many centralized cases, including case lists, attorney lists, party names, case management orders and recommendations,

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<sup>&</sup>lt;sup>1</sup> http://www.judiciary.state.nj.us/mass-tort/index.htm

The Honorable Glenn A. Grant December 30, 2009 Page 3.

judicial and staff assignments, and event calendars. As such, the Information Center provides significant public access to information about centralized cases and can be an influence on public opinion.

II. The Nomenclature Used Within R. 4:38A, the Guidelines, and the Information Center is Unnecessarily Prejudicial to Defendants and Should Be Revised in Favor of Neutral Nomenclature.

Although  $\underline{R}$ . 4:38A, the Guidelines, and the Information Center all are designed to identify and manage cases that should be centralized for case management, these resources unfairly refer to such cases as "mass torts." Because cases can be centralized for case management long before any court determines liability, damage or defect, the court system should refer to such cases in a more neutral manner than "mass torts."

A "mass tort" designation can have potentially negative ramifications for defendants and the public alike. For defendants, the publicity of a mass tort designation threatens business reputation and the ability to market and provide beneficial products. The phrase "mass tort" unnecessarily conveys a message that the product at issue is defective and has caused multiple harms. The press too often relies upon sound bytes to sensationalize an otherwise dull story. If a product is publicized as part of a "mass tort," not only does the product brand suffer significant harm, but the defendant itself may suffer harm by association. Unfortunately, the defendant incurs the costs associated with the negative press, and the loss of good will, long before the merits of the cases are sufficiently tested.

A "mass tort" designation can have undue negative effects on the public as well.

The Honorable Glenn A. Grant December 30, 2009
Page 4.

For example, in the pharmaceutical industry, once a medication is classified as part of a "mass tort" program, patients who need and benefit from the subject medication may become fearful and discontinue its use despite the medication's important benefits. In such a case, patients who need the medication suffer even though there has been no adjudication of a defect. The negative effects are of even greater concern where the medication is the subject of multiple lawsuits as the result of an isolated issue affecting only a small population of users. Even if the courts ultimately determine that the medication lacked an adequate warning for the isolated issue, a "mass tort" designation can result in the medication's discontinued use by a much greater population of patients who benefit from the product and for whom the product is not defective.

A simple change in the way that the Court formally refers to centralized cases can help reduce the unfair damage to a product's reputation that can be caused by centralization. We suggest that the Court consider the formal elimination of its use of the phrase "mass tort" in favor of "centralized management." A designation of "centralized management" would more closely mirror the federal court's "MDL" or "multi-district litigation" designation. We feel that such a change would reduce the undue prejudice created by centralization under the current nomenclature, and encourage more parties to embrace centralized management. Moreover, such a change would provide flexibility in the event that the Court wants to centrally manage appropriate matters other than those now considered "mass torts." For example, benefits of centralized management may be equally appropriate for antitrust cases, cases involving

The Honorable Glenn A. Grant December 30, 2009 Page 5.

claims of consumer fraud, and many other types of cases that are currently coordinated for centralized management in the federal system.

It appears that the Court already has begun using the phrase "centralized management" for new designations. *See eg.*, the Stryker Implant and Zelnorm litigations.<sup>2</sup> NJDA believes that the Court understands the prejudice created by the old system and is moving to remedy the unnecessary prejudice. We applaud this effort, and urge the Court to formalize the change in its designations and in its nomenclature moving forward.

Changing the nomenclature would be relatively simple. For instance,  $\underline{R}$ : 4:38A could be revised as follows:

RULE 4:38A. Centralized Management

The Supreme Court may designate a case or category of cases to receive centralized management in accordance with criteria and procedures promulgated by the Administrative Director of the Courts upon approval by the Court. Promulgation of the criteria and procedures will include posting in the Centralized Management Information Center on the Judiciary's Internet website (www.judiciary.state.nj.us).

The judiciary's Information Center could be called the "Centralized Management Information Center." The "Mass Tort Guidelines and Criteria for Designation" could become the "Centralized Management Guidelines and Criteria for Designation." We believe that the changes would be simple to implement, would remedy a long-standing bias in the system, and would help

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<sup>&</sup>lt;sup>2</sup> http://www.judiciary.state.nj.us/mass-tort/index.htm